Form PTO-1449 1997

INFORMATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number	203442107020
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Application Number 08/443,982

Applicant

VISHVA M. DIXIT et al.

Filing Date May 18, 1995

Group Art Unit 1807 1646

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
# R	1.	07/28/87	4,683,195	Mullis et al.	435	م	
	2.	07/28/87	4,683,202	Mullis	435	91	
	3.	06/28/88	4,754,065	Levenson et al.	562	564	
#R	4.	01/24/89	4,800,159	Mullis et al.	435	172.3	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translat YES 1	ion NO
AR	5.	12/23/93	WO 93/25685	PCT	Ī -			
	6.	12/23/93	WO 93/25694	PCT				
	7.	08/18/94	WO 93/18317	PCT				,
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	9.	10/27/94	WO 94/24297	PCT				
	10.	11/10/94	WO 94/25621	PCT				
	11.	12/08/94	WO 94/27583	PCT				
	12.	01/25/96	WO 96/01642	PCT				·
	13.	6/20/96	WO 96/18641	PCT				
	14.	7/11/96	WO 96/20721	PCT				
	15.	8/29/96	WO 96/25945	PCT				
	16.	11/21/96	WO 96/36698	PCT				
	17.	12/19/96	WO 96/40713	PCT				
X) R	18.	2/6/97	WO 97/03998	PCT	1	4		

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
AR.	19.	Allison et al., "The yin and yang of T cell costimulation" Science (1995) 270:932-933.
PR	20.	Barres et al., "Cell death and control of cell survival in the oligodendrocyte lineage" Cell (1992) 70:31-46.

EXAMINER:

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DATE CONSIDERED: 3/8/9 8

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Form PTO-1449	Docket Number 203442107020	Application Number 08/443,982	
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	•	OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)			
Examiner Initials	Ref. No.	Title			
Beidler et al., "The baculovirus p35 protein inhibits fas- and tumor necrosis factor-ind apoptosis" J. Biol. Chem. (1995) 270:16526-16528.					
	22.	Blau et al., "Molecular medicine: Gene therapy - a novel form of drug delivery" N. Eng. J. Med. (1995) 333:1204-1207.			
	23.	Bose et al., "Ceramide synthase mediates daunorubicin-induced apoptosis: An alternative mechanism for generating death signals" Cell (1995) 82:405-414.			
	24.	Boudreau et al., "Suppression of ICE and apoptosis in mammary epithelial cells by extracellular matrix" Science (1995) 267:891-893.			
	25.	Boulakia et al., "Bcl-2 and adenovirus E1B 19 kDa protein prevent E1A-induced processing of CPP32 and cleavage of poly(ADP-ribose) polymerase" Oncogene (1996) 12:529-535.			
	26.	Bump et al., "Inhibition of ICE family proteases by baculovirus antiapoptotic protein p35" Science (1995) 269:1885-1888.			
	27.	Casciola-Rosen et al., "Specific cleavage of the 70-kDa protein component of the U1 small nuclear ribonucleoprotein is a characteristic biochemical feature of apoptotic cell death" <u>J. Biol. Chem.</u> (1994) <u>269</u> :30757-30760.			
	28.	Chinnaiyan et al., "FADD/MORT1 is a common mediator of CD95 (Fas/APO-1) and tumor necrosis factor receptor-induced apoptosis" <u>J. Biol. Chem.</u> (1996) <u>271</u> :4961-4965.			
	29.	Chinnaiyan et al., "Molecular ordering of the cell death pathway" <u>J. Biol. Chem.</u> (1996) 271:4573-4576.			
	30.	Chinnaiyan et al. "Signal Transduction by DR3, a Death Domain-Containing Receptor Related to TNFR-1 and CD95" <u>Science</u> (1996) <u>274</u> :990-992.			
	31.	Clem et al., "Prevention of apoptosis by a baculovirus gene during infection of insect cells" Science (1991) 254:1388-1390.			
	32.	Clem et al., "Control of programmed cell death by the baculovirus genes p35 and iap" Mol. & Cell. Biol. (1994) 14:5212-5222.			
	33.	Cleveland et al., "Contenders in FasL/TNF death signaling" Cell (1995) 81:479-482.			
	34.	Correll et al., "Production of human glucocerebrosidase in mice after retroviral gene transfer into multipotential hematopoietic progenitor cells" Proc. Natl. Acad. Sci. USA (1989) 86:8912-8916.			
20 R	35.	Darmon et al., "Activation of the apoptotic protease CPP32 by cytotoxic T-cell-derived granzyme B" Nature (1995) 377:446-448.			

EXAMINER: Daniel Romes

DATE CONSIDERED: 3/8/88

Form PTO-1449

- INFORMATION DISCLOSURE CITATION
IN AN APPLICATION
(Use several sheets if necessary)

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Group Art Unit 1801

OTHER DOCUMENTS

			OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)
Exam Initia		Ref. No.	Title
			Dixit et al., "Tumor necrosis factor-α induction of novel gene products in human endothelial cells including a macrophage-specific chemotaxin" J. Biol. Chem. (1990) 265:2973-2978.
37.		37.	Duan et al., "ICE-LAP3, a novel mammalian homologue of the <i>Caenorhabditis elegans</i> cell death protein CED-3 is activated during Fas- and tumor necrosis factor-induced apoptosis" <u>J. Biol. Chem.</u> (1996) <u>271</u> :1621-1625.
		38.	Ellis et al., "Genetic control of programmed cell death in the nematode <i>C. elegans</i> " Cell (1986) 44:817-829.
		39.	Faucheu et al., "A novel human protease similar to the interleukin-1β converting enzyme induces apoptosis in transfected cells" EMBO J. (1995) 14:1914-1922.
		40.	Fernandes-Alnemri et al., "CPP32, a novel human apoptotic protein with homology to <i>Caenorhabditis elegans</i> cell death protein Ced-3 and mammalian interleukin-1β-converting enzyme" J. Biol. Chem. (1994) 269:30761-30764.
		41.	Fernandes-Alnemri et al., "Mch2, a new member of the apoptotic Ced-3/Ice cysteine protease gene family" Cancer Res. (1995) 55:2737-2742.
		42.	Fernandes-Alnemri et al., "Mch3, a novel human apoptotic cysteine protease highly related to CPP32" Cancer Res. (1995) 55:6045-6052.
·		43.	Finkel et al., "Apoptosis occurs predominantly in bystander cells and not in productively infected cells of HIV- and SIV-infected lymph nodes" <u>Nature Med.</u> (1995) 1:129-134.
		44.	Fisher et al., "Dominant interfering Fas gene mutations impair apoptosis in a human autoimmune lymphoproliferative syndrome" Cell (1995) 81:935-946.
		45.	Gagliardini et al., "Prevention of vertebrate neuronal death by the <i>crmA</i> gene" <u>Science</u> (1994) <u>263</u> :826-828.
		46.	Gooding, "Virus proteins that counteract host immune defenses" Cell (1992) 71:5-7.
		47.	Hanabuchi et al., "Fas and its ligand in a general mechanism of T-cell-mediated cytotoxicity" Proc. Natl. Acad. Sci. USA (1994) 91:4930-4934.
		48.	Henderson et al., "Epstein-Barr virus-coded BHRF1 protein, a viral homologue of Bcl-2, protects human B cells from programmed cell death" <u>Proc. Natl. Acad. Sci. USA</u> (1993) <u>90</u> :8479-8483.
		49.	Hengartner, "Life and death decisions: <i>ced-9</i> and programmed cell death in <i>Caenorhabditis elegans</i> " Science (1995) 270:931.
*		50.	Hsu et al., "TRADD-TRAF2 and TRADD-FADD interactions define two distinct TNF receptor 1 signal transduction pathways" <u>Cell</u> (1996) <u>84</u> :299-308.

EXAMINER:

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DATE CONSIDERED:

3/8/58

Form PTO-1449	Docket Number 203442107020	Application Number 08/443,982	
- INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant VISHVA M. DIXIT et al.		
(Use several sheets if necessary)	Filing Date May 18, 1995	Group Art Unit 1801	

OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.) Title Ref. Examiner **Initials** No. Hu et al. "A Novel Family of Viral Death Effector Domain-containing Molecules that Inhibit 51. Both CD-95- and Tumor Necrosis Factor Receptor-1-induced Apoptosis" J. Biol. Chem. MR (1997) 272:9621-9624. Hynes et al., "A target for tumour-directed therapy" Nature Medicine (1995) 1:631-632. 52. Itoh et al., "Effect of bcl-2 on Fas antigen-mediated cell death" J. Immunol. (1993) 151:621-53. 627. Iwai et al., "Differential expression of bcl-2 and susceptibility to anti-Fas-mediated cell death 54. in peripheral blood lymphocytes, monocytes, and neutrophils" Blood (1994) 84:1201-1208. Ju et al., "Participation of target Fas protein in apoptosis pathway induced by CD4⁺ Th1 and 55. CD8⁺ cytotoxic T cells" Proc. Natl. Acad. Sci. USA (1994) 91:4185-4189. Kägi et al., "Fas and perforin pathways as major mechanisms of T cell-mediated 56. cytotoxicity" Science (1994) 265:528-530. Kamens et al., "Identification and characterization of ICH-2, a novel member of the 57. interleukin -1β-converting enzyme family of cysteine proteases" J. Biol. Chem. (1995) 270:15250-15256. Kaufmann et al., "Specific proteolytic cleavage of poly(ADP-ribose) polymerase: An early 58. marker of chemotherapy-induced apoptosis" Cancer Res. (1993) 53:3976-3985. King et al., "Signaling for death of lymphoid cells" Current Opinion in Immunol. (1993) 59. 5:368-373. Komiyama et al., "Inhibition of interleukin-1β converting enzyme by the cowpox virus 60. serpin CrmA" J. Biol. Chem. (1994) 269:19331-19337. Kuby, "Immunology" W.H. Freeman and Company, N.Y. (1992) 257 61. Kuida et al., "Altered cytokine export and apoptosis in mice deficient in interleukin-1β 62. converting enzyme" Science (1995) 267:2000-2003. Kumar et al., "Protection from tumor necrosis factor-mediated cytolysis by overexpression of 63. plasminogen activator inhibitor type-2" J. Biol. Chem. (1991) 266:20960-20964. Kumar et al., "Induction of apoptosis by the mouse Nedd2 gene, which encodes a protein 64. similar to the product of the Caenorhabditis elegans cell death gene ced-3 and the X R mammalian IL-1β-converting enzyme" Genes & Devel. (1994) 8:1613-1626.

EXAMINER: DATE CONSIDERED: 3/8/9	' K

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Form PTO-1449	Docket Number 203442107020	Application Number 08/443,982
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant VISH	VA M. DIXIT et al.
(Use several sheets if necessary)	Filing Date May 18, 1995	Group Art Unit 1801

OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.) Ref. Title Examiner **Initials** No. Laherty et al. "Human T cell leukemia virus Type I tax and phorbol 12-myristate 13-acetate 65. induce expression of the A20 zinc finger protein by distinct mechanisms involving nuclear SAI R factor KB" J. Biol. Chem. (1993) 268:5032-5039. Lazebnik et al., "Cleavage of poly(ADP-ribose) polymerase by a proteinase with properties 66. like ICE" Nature (1994) 371:346-347. Li et al., "Mice deficient in IL-1β-converting enzyme are defective in production of mature 67. IL-1β and resistant to endotoxic shock" Cell (1995) 80:401-411. Liston et al., "Suppression of apoptosis in mammalian cells by NAIP and a related family of 68. IAP genes" Nature (1996) 379:349-353. Margolick et al., "Failure of T-cell homeostatis preceding AIDS in HIV-1 infection" Nature 69. Medicine (1995) 1:674-680. Martin et al., "Biochemical characterization of programmed cell death in NGF-deprived 70. sympathetic neurons" J. Neurobiol. (1992) 23:1205-1220. Martinou et al., "Viral proteins E1B19K and p35 protect sympathetic neurons from cell death 71. induced by NGF deprivation" J. Cell Biol. (1995) 128:201-208. McElvaney et al., "IL-6 release and airway administration of human CFTR cDNA 72. adenovirus vector" Nature Medicine (1995) 1:182-184. Miller et al., "Improved retroviral vectors for gene transfer and expression" BioTechniques 73. (1989) 7:980-990. Milner, "DNA damage, p53 and anticancer therapies" Nature Medicine (1995) 1:879-880. 74. Moss, "Poxviridae and their reproduction" Virology, 2nd ed., Fields, B.N. et al., eds., Raven 75. Press, New York (1990) Chapter 74, pp. 2079-2111. Munday et al., "Molecular cloning and pro-apoptotic activity of ECE_{rel}II and ICE_{rel}III, 76. members of the ICE/CED-3 family of cysteine proteases" J. Biol. Chem. (1995) 270:15870-15876. Na et al., "D4-GDI, a substrate of CPP32, is proteolyzed during Fas-induced apoptosis" <u>J.</u> 77. Biol. Chem. (1996) 271:11209-11213. Nicholson, "ICE/CED3-like proteases as therapeutic targets for the control of inappropriate **78**. apoptosis" Nature Biotechnol. (1996) 14:297-301. Nicholson et al., "Identification and inhibition of the ICE/CED-3 protease necessary for 79. SAR mammalian apoptosis" Nature (1995) 376:37-43.

EXAMINER: DATE CONSIDERED: 3/8/98

Form PTO-1449	Docket Number 203442107020	Application Number 08/443,982
· INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant VISHVA M	i. DIXIT et al.
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		OTHER DOCHMENTS		
		OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)		
Examiner Initials	Ref. No.	Title		
/ D V	80.	Orkin, et al. "Report and recommendation of the panel to assess the NIH investment in		
湖足		research on gene therapy"(1995)		
	81.	Paigen, "A miracle enough: the power of mice" Nature Medicine (1995) 1:215-220.		
	82.	Pan et al. "The Receptor for the Cytotoxic Ligand TRAIL" Science (1997) 276:111-113.		
	83.	Pantaleo et al., "Apoptosis in HIV infection" Nature Med. (1995) 1:118-120.		
	84.	Peter et al., "CD95 (APO-1/FAS)-associating signalling proteins" Cell Death and Differentiation (1996) 3:161-170.		
	85.	Pickup et al., "Hemorrhage in lesions caused by cowpox virus is induced by a viral protein		
		that is related to plasma protein inhibitors of serine proteases" Proc. Natl. Acad. Sci. (1986) 83:7698-7702.		
	86.	Rabizadeh et al., "Expression of the baculovirus <i>p35</i> gene inhibits mammalian neural cell death" <u>J. Neurochem.</u> (1993) <u>61</u> :2318-2321.		
	87.	Ray et al., "Viral inhibition of inflammation: Cowpox virus encodes an inhibitor of the		
	interleukin-1β converting enzyme" Cell (1992) 69:597-604.			
	88.	Roederer, "T-cell dynamics of immunodeficiency" Nature Medicine (1995) 1:621-622.		
	89.	Rothe et al., "TRAF2-mediated activation of NF-kB by TNF receptor 2 and CD40" Science (1995) 269:1424-1427.		
	90.	Rothe et al., "The TNFR2-TRAF signaling complex contains two novel proteins related by baculoviral inhibitor of apoptosis proteins" Cell (1995) 83:1243-1252.		
	91.	Roy et al., "The gene for neuronal apoptosis inhibitory protein is partially deleted in individuals with spinal muscular atrophy" [Cell (1995) 80:167-178.		
,	92.	Ruggiero et al., "Protection from tumor necrosis factor cytotoxicity by protease inhibitors" Cellular Immunol. (1987) 107:317-325.		
	93.	Schlegel et al., "CPP32/apopain is a key interleukin 1β converting enzyme-like protease involved in Fas-mediated apoptosis" J. Biol. Chem. (1996) 271:1841-1844.		
	94.	Smith et al. "CrmA expression in T lymphocytes of transgenic mice inhibits CD95		
		(Fas/APO-1)-transduced apoptosis, but does not cause lymphadenopathy or autoimmune		
		disease" The EMBO Journal (1996) <u>15</u> :5167-5176		
	95.	Soares, GenBank Accension No. T10341 (1994)		
	96.	Stalder et al., "Fas antigen is the major target nolecule for CD4 ⁺ T cell-mediated		
		cytotoxicity" <u>J. Immunol.</u> (1994) <u>152</u> :1127-1133.		
A)R	97.	Stinchcomb, "Constraining the cell cycle: Regulating cell division and differentiation by gene therapy" Nature Medicine (1995) 1:1004-1006.		
<u> </u>				

EXAMINER: Samil Romes DATE CONSIDERED: 3/8/98

Form PTO-1449	Docket Number 203442107020	Application Number 08/443,982	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant VISHVA M	. DIXIT et al.	
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		OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)		
Examiner	Ref.	Title		
Initials	No.			
ZAR_	98.	Strasser, "Death of a T cell" <u>Nature</u> (1995) <u>373</u> :385-386.		
	99.	Suffys et al., "Involvement of a serine protease in tumour-necrosis-factor-mediated		
		cytotoxicity" Eur. J. Biochem. (1988) <u>178</u> :257-265.		
	100.	Sugimoto et al., "Baculovirus <i>p35</i> prevents developmentally programmed cell death and rescues a <i>ced-9</i> mutant in the nematode <i>Caenorhabditis elegans</i> " EMBO J. (1994) <u>13</u> :2023-2028.		
	101.	Tamura et al., "An IRF-1-dependent pathway of DNA damage-induced apoptosis in mitogenactivated T lymphocytes" Nature (1995) 376:596-599.		
	102.	Tanaka et al., "Fas ligand in human serum" Nature Medicine (1996) 2:317-322.		
	103.	Tewari et al., "CrmA-inhibitable cleavage of the 70-kDa protein component of the U1 small nuclear ribonucleoprotein during Fas- and tumor necrosis factor-induced apoptosis" J. Biol. Chem. (1995) 270:18738-18741.		
	104.	Tewari et al., "Yama/CPP32β, a mammalian homolog of CED-3, is a CrmA-inhibitable protease that cleaves the death substrate poly(ADP-ribose) polymerase" Cell (1995) 81:801-809.		
	105.	vanBockxmeer et al., "Premature ischaemic heart disease and the gene for coagulation factor V" Nature Medicine (1995) 1:185.		
	106.	Verheij et al., "Requirement for ceramide-initiated SAPK/JNK signalling in stress-induced apoptosis" Nature (1996) 380:75-79.		
	107.	Vermes et al., "Apoptosis and programmed cell death in health and disease" (1994) Academic Press, Inc., pp. 177-246.		
	108.	Vito et al., 'Interfering witih apoptosis: Ca ²⁺ -binding protein ALG-2 and Alzheimer's disease gene ALG-3" Science (1996) 271:521-525.		
	109.	Walker et al., "Crystal structure of the cysteine protease interleukin-1β-converting enzyme:		
		A (p20/p10) ₂ homodimer" <u>Cell</u> (1994) <u>78</u> :343-352.		
	110.	Wang et al., "Ich-1, an Ice/ced-3-related gene, encodes both positive and negative regulators of programmed cell death" Cell (1994) 78:739-750.		
	111.	Wang et al., "Cleavage of sterol regulatory element binding proteins (SREBPs) by CPP32 during apoptosis" EMBO J. (1996) 15:1012-1020.		
	112.	Westendorp et al., "Sensitization of T cells to CD95-mediated apoptosis by HIV-1 Tat and gp120" Nature (1995) 375:497-500.		
	113.	White, "Regulation of apoptosis by the transforming genes of the DNA tumor virus		
		adenovirus (43631)" P.S.E.B.M. (1993) 204:30-39.		
	114.	Whyte et al., "The last cut is the deepest" Nature (1995) 376: 17-18.		
DR	Williams et al., "Apoptotic cell death induced by intracellular proteolysis" J. Immunol. (1994) pp. 4247-4255.			
	EXAMINER: DATE CONSIDERED: 3/8/88			
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in				

Form PTO-1449	Docket Number 203442107020	Application Number 08/443,982	
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		OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)		
Examiner Initials	Ref. No.	Title		
AR	116.	Wilson et al., "Structure and mechanism of interleukin-1β converting enzyme" Nature (1994) 370:270-275.		
	117.	Woo, "Apoptosis and loss of renal tissue in polycystic kidney diseases" N. Eng. J. Med. (1995) 333:18-25.		
	118.	Wu et al., "Interaction of the erythropoietin and stem-cell-factor receptors" <u>Nature</u> (1995) 377:242-246.		
	119.	Xue et al., "Inhibition of the <i>Caenorhabditis elegans</i> cell-death protease CED-3 by a CED-3 cleavage site in baculovirus p35 protein" Nature (1995) 377:248-251.		
	120.	Zheng et al., "Induction of apoptosis in mature T cells by tumour necrosis factor" <u>Nature</u> (1995) <u>377</u> :348-351.		
#R	121.	EMBL Database, Accension number PIR P9135 Kotwal JG, Moss B (12 Jan 1990)		

EXAMINER: DATE CONSIDERED: 3/8/98